FEB 2 3 2004 K040166

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	DePuy Orthopaedics, Inc. P.O. Box 988 700 Orthopaedic Drive Warsaw, IN 46581-0988
510(k) CONTACT:	Cheryl Hastings Director, Regulatory Affairs
TRADE NAME:	DePuy Sigma XLK Tibial Inserts
COMMON NAME:	Total Knee Joint Replacement Prosthesis
CLASSIFICATION:	888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis; Class II
DEVICE PRODUCT CODE:	87 JWH
SUBSTANTIALLY EQUIVALENT DEVICE:	DePuy Sigma Tibial Inserts – K033272 Johnson & Johnson (now DePuy) Darwin Knee System – K943462, K950010, K961685, K971189

DEVICE DESCRIPTION:

The DePuy Sigma XLK Tibial Inserts are posterior lipped, cruciate retaining or stabilized tibial inserts with the same design and intended use as the tibial inserts cleared in K033272. The subject inserts are manufactured from XLK Crosslinked Polyethylene. The Sigma XLK Tibial Inserts are intended for use with the Sigma Co-Cr Tibial Trays previously cleared in K032151, and the Darwin femoral components, previously cleared in K943462.

When tested with DePuy Sigma Co-Cr Tibial Trays, the DePuy XLK Sigma Tibial Inserts exhibit 89% less gravimetric wear than previously cleared Johnson & Johnson Darwin tibial inserts tested with Johnson & Johnson PFC tibial trays. This claim is supported by 5 million cycle knee simulator wear data. The products tested were Size 3 Sigma Co-Cr Tibial Trays mated with Size 3, 10mm cruciate retaining Sigma XLK Tibial Inserts (n= 3) compared to Size 3 PFC Titanium Trays mated with Size 3, 10mm cruciate retaining Darwin (PFC Sigma) Tibial Inserts (n= 6). Both sets of inserts were articulated against Size 3 cast Co-Cr PFC Sigma cruciate retaining, non-porous coated femoral components. All tibial trays and femoral components were sterilized using gamma irradiation. The Sigma XLK inserts were sterilized using gas plasma sterilization. The Darwin Tibial Inserts were sterilized using gamma vacuum foil (GVF) sterilization and packaging. Testing was conducted on a AMTI multi-axial displacement controlled knee joint simulator using bovine serum as a lubricant.

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The results of in-vitro wear tests have not been shown to correlate with clinical wear mechanisms.

INTENDED USE AND INDICATIONS:

The Sigma XLK Tibial Inserts are intended for use in total knee replacement surgery for patients suffering from severe pain and disability due to permanent structural damage resulting from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, pseudogout, trauma or failed prior surgical intervention.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Sigma XLK Tibial Inserts have the same design and intended use as the Sigma Inserts cleared in K033272. Mechanical testing shows that the Sigma XLK Tibial Inserts perform similarly to the Sigma and Darwin Inserts but exhibit less wear in knee simulator testing. Based on similarities in design, material, manufacturing method and intended use, DePuy believes that the Sigma Tibial XLK Inserts are substantially equivalent to the previously cleared Sigma and Darwin Tibial Inserts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 3 2004

Ms. Cheryl K. Hastings
Director, Regulatory Affairs
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K040166
Trade/Device Name: DePuy Sigma XLK Tibial Inserts
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JWH
Dated: January 24, 2004
Received: January 26, 2004

Dear Ms. Hastings:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040166

Device Name: DePuy Sigma XLK Tibial Inserts

Indications for Use:

The Sigma XLK Tibial Inserts are intended for use in total knee replacement surgery for patients suffering from severe pain and disability due to permanent structural damage resulting from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, pseudogout, trauma or failed prior surgical intervention.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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(Posted November 13, 2003)